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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/807,837

03/24/2004

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03-02

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05/07/2007

EXAMINER

STOICA, ELLY GERALD

ART UNIT PAPER NUMBER

1647

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/807,837	Applicant(s) XU ET AL.	
	Examiner Elly-Gerald Stoica	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 23-54 and 61-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-22 and 55-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the application

1. The amendment, filed 02/15/2007 has been entered. Claims 1-73 are pending. Claims 1-7, 23-54, and 61-73 are withdrawn as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 8-22 and 55-60 are under examination.

Response to Remarks/Arguments

2. The objection to claims 8-13 is maintained. While the Applicant removed the dependency of the claim 8-13 from the non-elected claim 1, the amended claim 8 incorporates non-elected subject matter from claim 1. The amended claims 9-13 are now dependent on claim 8, which incorporates non-elected subject matter from claim 1. The objection to claims 56-57 is maintained since the dependency of the claims from claim 55, which contains non-elected subject matter, is still present.

The claims 61-73 are objected to as having incorrect status identifiers. While the claims were withdrawn pursuant to 37 CFR 1.142 (b) in the office action of 08/18/2006 as being drawn to nonelected inventions, they are still identified as original. Appropriate correction is required.

As correctly pointed out by the Applicant in the reply filed on 02/15/2007, the claims will be examined fully only with respect to the elected species.

Maintained rejections

35 U.S.C. § 103 (a)

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8-10, 12, 13, 15-18, 20, 21, 55-57, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Busfield (US 2002/0164689A1 in view of "Hopp et al." (Hopp, TP and Woods, KR, Proc. Natl. Acad. Sci. USA: 78, 3824-28, 1981) and in further view of Lok et al. (US Patent 5,965,704.). The claims are drawn to an antibody to a polypeptide produced by a method comprising: inoculating an animal with a polypeptide consisting of the amino acid sequence of SEQ ID NO: 3 from amino acid number 1 (Pro), to amino acid number 6 (Asp), wherein the polypeptide elicits an immune response in the animal to produce the antibody and isolating the antibody from the animal, and wherein the antibody, which binds to a polypeptide of SEQ ID NO: 2 or SEQ ID NO: 3 reduces the activity of either IL-20 (SEQ ID NO:8) or IL-22 (SEQ ID NO:6). The antibody reduces the pro-inflammatory activity of either IL-20 (SEQ ID NO:8) or IL-22 (SEQ ID NO: 6) or both and the antibody is: (a) a polyclonal antibody, (b) a murine monoclonal antibody, (c) a humanized antibody derived from (b), (d) an antibody fragment, or (e) a human monoclonal antibody and comprises a radionuclide, enzyme, substrate, cofactor, fluorescent marker, chemiluminescent marker, peptide tag, magnetic particle, or toxin. This rejection is maintained for the reasons of record in the prior Office action.

Applicant's arguments filed 01/18/2007 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Specifically, the argument that Busfield teaches away from the proposition that the best antigenicity is obtained using hexapeptides is rejected since Hopp et al. teach requirements for the best antigenicity. The hexapeptide best antigenic fragment based on a antigenicity analysis and is comprised by the longer peptide fragment of Busfield et al. Busfield does not provide a detailed analysis (just that the peptide have to be located in a hydrophilic region and the fragment) but Hopp et al. actually offer scientific data to pick the best antigenic fragment which is present in the Seq. Id. No: 2 of Busfield et al.

The limitations that the antibody against the IL-22 RA reduces the activity of either IL 20 or IL-22 or both are inherently present as a consequence of the structure of the antibody. Therefore the argument that the limitation is not disclosed in the Busfield or Hopp et al. (or Lok et al) references is not persuasive.

5. Claims 11, 14, 19, 22, 58, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Busfield (US 2002/0164689A1 in view of "Hopp et al." (Hopp, TP and Woods, KR, Proc. Natl. Acad. Sci. USA: 78, 3824-28, 1981) and in further view of Lok et al. (US Patent 5,965,704.) and Chen et al. (Chen AM, Scott, MD, BioDrugs, 2001; 15(12): 833-47). The claims are drawn to an antibody to a polypeptide produced by a

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method comprising: inoculating an animal with a polypeptide consisting of the amino acid sequence of SEQ ID NO: 3 from amino acid number 1 (Pro), to amino acid number 6 (Asp), wherein the polypeptide elicits an immune response in the animal to produce the antibody and isolating the antibody from the animal, and wherein the antibody, which binds to a polypeptide of SEQ ID NO: 2 or SEQ ID NO: 3 reduces the activity of either IL-20 (SEQ ID NO:8) or IL-22 (SEQ ID NO:6). The antibody reduces the pro-inflammatory activity of either IL-20 (SEQ ID NO:8) or IL-22 (SEQ ID NO: 6) or both and the antibody is: (a) a polyclonal antibody, (b) a murine monoclonal antibody, (c) a humanized antibody derived from (b), (d) an antibody fragment, or (e) a human monoclonal antibody and comprises a radionuclide, enzyme, substrate, cofactor, fluorescent marker, chemiluminescent marker, peptide tag, magnetic particle, or toxin. The antibodies are further PEGylated. This rejection is maintained for the reasons of record in the prior Office action.

Applicant's arguments filed 01/18/2007 have been fully considered but they are not persuasive. As presented supra, the independent claims 8, 15, and 55 are rejected as obvious; the dependent claims 11, 14, 19, 22, 58, and 60 are likewise obvious.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 8-22 and 55-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-22 and 55-60 of copending Application No. 11/256499. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same subject matter in both the instant and co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



LORRAINE SPECTOR
PRIMARY EXAMINER